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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,454	08/24/2001	Carol J. Collins	NEU-40	2232

27777 7590 07/22/2005  
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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/938,454

Applicant(s)

COLLINS ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION****Status of the Application**

Receipt of Applicant's Response, Arguments/Remarks and the request for extension of time (2 months-granted), all filed 05/05/05 is acknowledged. Examiner does *not* acknowledge receipt of the second Supplemental Information Disclosure Statement (IDS), which Applicant stated was filed on 08/30/03, as no IDS submission filed on that date is of record.

Claims 1-24 are pending. No amendments to the claims have been made. Claims 1-24 remain rejected.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunkel *et al.* (US Pat. No. 6,524,598 B2).**

Sunkel *et al.* teach cosmetic compositions comprising organopolysiloxane elastomers and silicone oils wherein the composition may be in the form of a foundation, *mascara*, eye shadows, powders, blushers, lip color and the like (see reference column 2, lines 35-55); Examples, particularly Example II and claims 1, 13 and 20.

Silicone oils include *cyclomethicone* (see Examples). Film-forming agents taught include *polyurethanes* (col. 12, lines 8-11). Pigments, such as *mica* are listed at column 16, line 65 – col.

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17, line 35. Solidifying agents (*i.e.*, waxes) are present at a concentration of from about 0 to about 90% (col. 14, lines 55-65). Exemplary organopolysiloxanes are taught at column 3, line 66 – col. 4, line 13.

Example II at column 23 demonstrates a mascara composition comprising elastomer gels, silicone oils, pigments and the like. The mascara composition is applied to the lashes and/or eyebrows to provide softening, moisturization and conditioning.

The prior art explicitly teaches the use of organopolysiloxane elastomers, silicone oils and gels in mascara formulations. The Applicant's have not demonstrated any criticality based on the claimed limitation of less than about 1%, by weight, of wax. Sunkel *et al.* at column 14, lines 55-65, teach that solidifying agents (*i.e.*, waxes) are present at a concentration of from about 0 to about 90%. The formulations of Sunkel *et al.* are not limited to the Examples recited in the '598 patent, which include the use of wax, since generally, the solidifying agents (*i.e.*, waxes) can be contained at a concentration of from 0-90%, as taught by Sunkel *et al.* Therefore, based on the delineated teachings, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

**Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shukuzaki *et al.* (US Pat. No. 5, 266,321) in view of Sunkel *et al.* (US Pat. No. 6,524,598 B2).**

Shukuzaki *et al.* teach an oily make-up cosmetic comprising a silicone gel composition, which comprises a partially crosslinked organopolysiloxane polymeric compound and a low viscosity silicone oil (see reference column 2); (col.7); (col.8, lines 47-56); and examples. Specific examples of the low viscosity oils are: dimethylpolysiloxane,

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methyphenylpolysiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane and the like (col. 7, lines 3-16). Various cosmetic powders, such as mica can be included in the composition (col. 7, lines 32-45). The make-up cosmetic can be applied to a foundation, eye shadow, face powder, lip stick and the like and can take various forms including a solid, stick and the like (col. 8, lines 53-56).

Shukuzaki is deficient only in the sense that he does not explicitly teach the make-up cosmetic in the form of mascara.

*Sunkel et al.* teach cosmetic compositions comprising organopolysiloxane elastomers and silicone oils wherein the composition may be in the form of a foundation, *mascara*, eye shadows, powders, blushers, lip color and the like (see reference column 2, lines 35-55); Examples, particularly Example II and claims 1, 13 and 20.

It would have been obvious to one of ordinary skill in the pharmaceutical art at the time the invention was made to use the teachings of Sunkel *et al.* within the teachings of Shukuzaki *et al.* because Sunkel *et al.* explicitly teach cosmetic compositions comprising organopolysiloxane elastomers and silicone oils wherein the cosmetic composition may be in various forms, such as foundation, *mascara*, eye shadows, powders, lip color, blushers and the like and similarly, Shukuzaki *et al.* teach polyorganosiloxane elastomers and silicone oils formulated in a make-up cosmetic wherein the composition can be applied to foundations, eye shadows, face powder, lip stick and the like and can take various forms including a solid, stick. The expected result would be an improved, cosmetic composition, such as in the form of mascara, that provides softening, moisturizing and conditioning properties.

Prior Art made of record and deemed relevant by the Examiner:

US Pat. No. 5, 412,004      Tachibana *et al.*      02/1994

***Response to Arguments***

Applicant's arguments filed 05/05/05 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 1-24 over Sunkel *et al.* ('598) stating, "Applicants have discovered that the organosiloxane elastomer and silicone oil can be used in place of waxes in mascaras; waxes are not desirable in mascaras. Thus, there is criticality to having little to no wax, as recited in claim 1. The Office Action states that 'Sunkel *et al.* teach that solidifying agents (i.e., waxes) are present at a concentration of from about 0 to 90%'. However, Sunkel *et al.* relates to various types of cosmetic compositions. Sunkel *et al.* does not disclose, nor suggest, how one would make a mascara with 0% wax. Sunkel *et al.* teaches away from such a mascara set forth in Example II, which comprises 11.25% of wax. Sunkel does not teach mascara that comprises less than about 1%, by weight, of wax."

These arguments have been thoroughly considered, but were not found persuasive. Applicant's argument that 'waxes are not desirable in mascaras' is not persuasive since the mascara formulation of Sunkel *et al.* provides for softening, as well as moisturization and conditioning benefits to the mascara and thus, the waxes would not be considered as a negative component to the mascara formulation. Applicant's preference of employing organosiloxane elastomer rather than wax components does not impart patentability to the instant invention. As

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noted above, Sunkel et al. do teach that '0 to 90% of solidifying agents, of which waxes are included, can be present. Moreover, Applicant's argument that 'Sunkel et al. relates to various types of cosmetic compositions and they do not disclose, nor suggest, how one would make a mascara with 0% wax' is not persuasive since mascara is clearly amongst the 'various types of cosmetic compositions' disclosed by Sunkel et al. and thus the percent ranges of 0 to 90% solidifying agents (*i.e.*, wax), would also apply to the mascara cosmetic. While Sunkel et al. in Example II demonstrates a mascara formulation comprising greater than 1% wax or specifically, 11.25% wax, as stated by Applicant, it is the Examiner's position that the prior art teachings are not limited to the examples illustrated therein. The prior art clearly suggests and teaches that minute amounts (*i.e.*, 0%) of solidifying agents (*i.e.*, waxes) can be present. The teaching of "about 0%" of solidifying agents, of which wax is included, would clearly read on the 'less than about 1%, by weight, of wax' as instantly being claimed. Applicants have not demonstrated any surprising or unexpected results that accrue from the use of 'less than about 1%, by weight, of wax', as instantly claimed. The prior art recognizes and teaches mascara formulations that can comprise virtually no wax.

Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 1-24 over Shukuzaki et al. ('321) in view of Sunkel et al. ('598) stating, "Applicant's invention relates to a mascara that comprises less than about 1% by weight, of wax. Shukuzaki is silent with respect to mascaras. Sunkel et al. fails to disclose or suggest a mascara of claim 1, and teaches away from such a mascara.'

Applicant's arguments have been fully considered, but were not persuasive. Shukuzaki *et al.* teach the use of organopolysiloxane elastomers in various cosmetic forms, such as foundations, eye shadow, face powder, lipstick and the like. Admittedly, Shukuzaki is silent with respect to mascaras. However, Sunkel *et al.* remedies this only deficiency of Shukuzaki *et al.* by explicitly teaching organopolysiloxane elastomers in combination with silicone oils, contained in an array of cosmetic forms, which include, mascara, among others, such as foundations, eye shadow, face powder, lipstick and the like. The secondary reference of Sunkel demonstrates that the organopolysiloxane elastomers are suitable and effective in solid and semi-solid cosmetic formulations. Sunkel *et al.*, as delineated above, recognizes and teaches mascara formulations comprising minute amounts (*i.e.*, 0%) of solidifying agents, of which waxes are included. Thus, ample motivation is provided to one of ordinary skill in the art to incorporate organopolysiloxane elastomers in various cosmetic forms, particularly mascara formulations as taught by the prior art and claimed by Applicant.

Applicant argued, "The Office Action states on the bottom of page 7 that the 'prior art teaches the use of low viscosity silicone oils to provide for better make-up effects and superior stability'. No reference for such statement is provided in the Office Action. In any event, Applicants are claiming a mascara that (i) comprises a silicone gel that comprises an organosiloxane elastomer and a silicone oil and (ii) comprises less than about 1% by weight of wax. Neither Sunkel *et al.* nor Shukuzaki *et al.* disclose or suggest such a mascara."

With regards to Examiner's statement that 'better make-up effects and superior stability is provided by the prior art', Examiner directs Applicant to the Shukuzaki *et al.* reference, column 1, line 66 – col. 2, line 14.



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Applicant's argument that 'neither Sunkel et al. nor Shukuzaki et al. disclose or suggest such a mascara as claimed' is not persuasive, since as discussed above, the prior art teaches cosmetic formulations, such as mascara, comprising organopolysiloxane elastomers and silicone oils. The mascara composition provides for beneficial effects, such as softening, moisturization and conditioning of the lashes. The art also recognizes mascara formulations that can comprise no wax at all. Moreover, it is deemed obvious to one of ordinary skill in the art to determine suitable amounts of wax through routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Thus, given the explicit teachings of the prior art, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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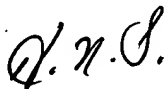
### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


H. N. Sheikh



Patent Examiner

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July 19, 2005



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